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Leidos IDIQ Ebola Project FY16 EAC

<i>Direct Labor & Fringe Benefits</i>	<i>Posted Expenses as of 4/29/16</i>	<i>Estimated to Completion</i>	<i>Total FY16 EAC</i>
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Non-responsive

Materials & Supplies

Non-responsive

Other Direct Costs

Non-responsive

UMinn Prev IV - Gilead

TBD

-

375,000

375,000

0/6 Inv Rec'd

Non-responsive

Capital Equipment

5610	Capital Equipment		210,962	355,196	566,158
	Subtotal-Capital Equipment		\$ 210,962	\$ 355,196	\$ 566,158

Indirect Costs

300	Materials, Equip & Subs	3.30%	\$ 213,318	\$ 798,989	\$ 1,012,307
400	General OH	29.08%	318,741	327,361	646,102
410	A/C OH	10.11%	110,814	113,811	224,625
500	G&A	1.04%	96,745	290,665	387,410
	Subtotal-Indirect Costs		\$ 739,619	\$ 1,530,826	\$ 2,270,444
	TOTAL ESTIMATED COST		\$ 9,404,028	\$ 28,241,972	\$ 37,646,000

- DOES NOT INCLUDE IMAGING PROJECT (MRI/CT MACHINES)

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Leidos Subcontractor and Consultant Costs

ON IDIQ TO14							
5780	Research Support	IDIQ Contract No.	Inv Through	Posted Expenses	Yet to be Invoiced	EAC	Notes:
Non-responsive							
	Uminn Prev IV - Gilead	TBD		-	375,000	375,000	0/6 Inv Rec'd; Est \$750k over a full year POP
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Leidos PREVAIL IV EAC for FY16

Direct Labor & Fringe Benefits			FY16 IDIQ ER	EAC	Assumptions
	Position				
5311	Leidos Labor		\$		Includes project IDs: 400 075 0014 0001 585 001 No accrued costs
110	Fringe	49.62%			
Subtotal-Direct Labor & Fringe Benefits			\$	\$	
Materials & Supplies					
5420	Occupational Clothing		\$	\$ 5,000	
5430	Biologicals		-	70,000	
5440	Controlled Materials		-		
5450	Industrial Supplies		-	10,000	
5453	Tools&Test Devices				
5455	Cleaning Supplies			5,000	
5460	Lab Supplies			90,000	
5470	Office Supplies			15,000	
5472	Freight			50,000	
5473	Telephone/wireless				
5476	Dues				
5477	Books				
5480	Computer Hardware			5,000	
5481	Computer Software				
Subtotal-Materials & Supplies			\$	\$ 250,000	
Other Direct Costs					
5511	Foreign Travel		\$		
5512	Scientific Travel				
5513	Administrative Travel				
5514	Training				
5515	Recruitment				
5516	Relocation Expenses				
5519	International Health Insurance				
5520	FCRF Seminars				
5550	Registration Fees				
5331	Direct Labor Overtime Premium				
5731	Postage				
5721	Vehicle Parts				
5735	Management Support Allocation				
5760	Service Maintenance Agreements				
5762	Software Support				
5764	Relocation of Equipment				
5570	Consultants				
5780	Research Support Services				
5790	Admin Support Services				
5875	Service-Interco Workorder				
5883	Non-SBA Funded				
6450	WH Industrial Supplies				
6460	WH Lab Supplies				
6470	WH Office Supplies				
Subtotal-ODC			\$	\$	
Shared Services					
5914	CMRP Support		\$	\$	
5928	Publications				
5970	Admin Support Charge Back				
5980	Work Orders				
Subtotal-Shared Services			\$	\$	
Capital Equipment					
5610	Capital Equipment		\$	\$ 78,000	
Subtotal-Capital Equipment			\$	\$ 78,000	
Indirect Costs					
300	Materials, Equip & Subs	3.30%	\$	\$ 10,824	
400	General OH	29.08%			
410	A/C OH	10.11%			
500	G&A	1.04%		3,524	
Subtotal-Indirect Costs			\$	\$ 14,348	
TOTAL ESTIMATED COST			\$	\$ 342,348	

Leidos IDIQ Ebola Project FY16 EAC

Direct Labor & Fringe Benefits			EAC as of 5/13 "Deep Dive"	Posted Expenses as of 7/20/16	Estimated to Completion	Current FY16 EAC	Change
	Position						
Non-responsive							
Materials & Supplies							
Non-responsive							
Other Direct Costs							
Non-responsive							
UMinn Prev IV - Gilead		T6D	187,500	-	212,263	212,263	24,763
Non-responsive							

Leidos Subcontractor and Consultant Costs

ON IDIQ TO14

5780	Research Support	IDIQ Contract No.	May EAC	Posted Expenses	Yet to be invoiced	EAC	Notes
Non-responsive							
Umnin Prev IV - Gilead		TBD	187 500	-	212 263	212 263	0/8 Inv Rec'd, Estimate is \$630k Feb '16 May '17
Non-responsive							

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Direct Labor & Fringe Benefits		May ER	May 1 EAC	July ER	FY16 EAC	Assumptions
Position						
53.1 Leidos Labor		\$		\$		Includes project IDs: 400 075 0014 0001 005 001 Costs as of 7/20/2016
110 Fringe	49.62%					
Subtotal-Direct Labor & Fringe Benefits		\$ -	\$ -	\$ -	\$ -	
Materials & Supplies						
5420 Occupational Clothing		\$	\$ 5,000	\$ 5,708	\$ 6,708	\$60k order pending for IRF
5430 Biologicals			70,000	34,251	125,689	
5440 Controlled Materials						
5450 Industrial Supplies			10,000	597	2,000	
5453 Tools&Test Devices						
5455 Cleaning Supplies			5,000	141	1,000	
5460 Lab Supplies			90,000	28,799	46,233	
5470 Office Supplies			15,000	3,248	6,000	
5472 Freight			50,000	32,028	50,000	
5473 Telephone/wireless						
5476 Dues						
5477 Books						
5480 Computer Hardware			5,000	1,955	6,761	
5481 Computer Software				4,389	4,389	
Subtotal-Materials & Supplies		\$ -	\$ 250,000	\$ 111,115	\$ 248,779	
Other Direct Costs						
55.1 Foreign Travel		\$				
5512 Scientific Travel						
5513 Administrative Travel						
55.4 Training						
5515 Recruitment						
5516 Relocation Expenses						
55.9 International Health Insurance						
5520 FCRF Seminars						
5550 Registration Fees						
533.1 Direct Labor Overtime Premium						
573.1 Postage						
5721 Vehicle Parts						
5735 Management Support Allocation						
5760 Service Maintenance Agreements						
5762 Software Support				\$		
5764 Relocation of Equipment						
5570 Consultants						
5780 Research Support Services						
5790 Admin Support Services						
5875 Service-Interco Workorder						
5883 Non-SBA Funded						
6450 WH Industrial Supplies						
6460 WH Lab Supplies						
6470 WH Office Supplies						
Subtotal-ODC		\$ -	\$ -	\$ -	\$ -	
Capital Equipment						
56.0 Capital Equipment		\$	\$ 78,000	\$	\$ 78,000	\$35k pending for Ace alert
Subtotal-Capital Equipment		\$ -	\$ 78,000	\$ -	\$ 78,000	
Indirect Costs						
300 Materials, Equip & Subs	3.30%	\$	\$ 10,824	\$ 3,667	\$ 10,784	
400 General OH	29.08%					
4.0 A/C OH	10.11%					
500 G&A	1.04%		3,524	1,194	3,511	
Subtotal-Indirect Costs		\$ -	\$ 14,348	\$ 4,861	\$ 14,294	
TOTAL ESTIMATED COST		\$ -	\$ 342,348	\$ 115,981	\$ 341,074	

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For the Period FY16 - FY20

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Leidos IDIQ Ebola Project Fixed Costs

Direct Labor & Fringe Benefits		Total FY16 EAC	FY17	FY18	FY19	FY20
Position						
5311 Leidos Labor		\$ 2,238,781	\$ 2,286,453	\$ 1,849,872	\$ 1,767,624	Non responsive
110 Fringe	49.62%	1,110,883	1,132,937	915,502	872,853	
Subtotal-Direct Labor & Fringe Benefits		\$ 3,349,665	\$ 3,419,390	\$ 2,765,373	\$ 2,640,477	
Materials & Supplies						
5420 Occupational Clothing		\$ 204	\$ 204	\$ 204	\$ 204	
5430 Biologicals		777	777	777	777	
5440 Controlled Materials				-		
5450 Industrial Supplies		20,000	20,000	20,000	10,000	
5453 Tools & Test Devices						
5455 Cleaning Supplies		200	200	200	200	
5460 Lab Supplies		2,000	2,000	2,000	2,000	
5470 Office Supplies		40,000	40,000	40,000	20,000	
5472 Freight		39,805	20,903	30,759	12,863	
5473 Telephone/wireless		45,801	78,516	78,516	58,887	
5476 Dues		150	750	300	300	
5477 Books						
5480 Computer Hardware		24,875	24,875	24,875	15,000	
5481 Computer Software						
Subtotal-Materials & Supplies		\$ 173,812	\$ 188,225	\$ 197,631	\$ 120,231	
Other Direct Costs						
5511 Foreign Travel		\$ 1,247,869	\$ 896,893	\$ 616,515	\$ 474,873	
5512 Scientific Travel		15,880	5,000	5,000	5,000	
5513 Administrative Travel		18,309	18,309	18,309	6,000	
5514 Training						
5515 Recruitment		3,846	4,000	4,000	2,000	
5516 Relocation Expenses			5,000	5,000		
5519 International Health Insurance		68,681	74,431	74,431	74,431	
5520 FCRF Seminars						
5550 Registration Fees		-	-			
5331 Direct Labor Overtime Premium		11,902	12,000	8,000	6,000	
5731 Postage		23	-	-	-	
5721 Vehicle Parts						
5735 Management Support Allocation						
5760 Service Maintenance Agreements				-		
5762 Software Support		3,000	3,000	3,000	1,500	
5764 Relocation of Equipment				-		
5570 Consultants		-	-	-	-	
5780 Research Support Services (TMG)	16X055Q	6,923,086	6,923,086	6,923,086	6,923,086	
5790 Admin Support Services		-	-	-	-	
5875 Service-Interco Workorder				-		
5883 (Non SBA Funded)						
6450 WH Industrial Supplies		1,000				
6460 WH Lab Supplies		1,000				
6470 WH Office Supplies		1,600				
Subtotal-ODC		\$ 8,296,195	\$ 7,941,719	\$ 7,657,341	\$ 7,492,890	
Capital Equipment						
5610 Capital Equipment		-	-	-	-	
Subtotal-Capital Equipment		\$ -	\$ -	\$ -	\$ -	
Indirect Costs						
300 Materials, Equip & Subs	3.30%	\$ 234,297	\$ 239,752	\$ 245,056	\$ 247,273	
400 General OH	29.08%	651,038	658,270	527,213	498,647	
410 A/C DH	10.11%	226,341	230,703	186,467	177,823	
500 G&A	1.04%	134,449	133,120	121,580	117,362	
Subtotal-Indirect Costs		\$ 1,246,124	\$ 1,261,845	\$ 1,080,317	\$ 1,041,105	
TOTAL ESTIMATED FIXED COSTS		\$ 13,065,796	\$ 12,811,179	\$ 11,700,663	\$ 11,294,703	
Check	Total Yearly Cost	34,989,401	32,731,729	25,542,153	23,733,856	
	Minus Fixed Costs	13,065,796	12,811,179	11,700,663	11,294,703	
	Total Variable Costs	21,923,605	19,920,550	13,841,490	12,439,154	

Based on IDIQ plus new CPMI
(Hassan Aug 2016-2018)

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Leidos PREVAII IV - Liberia Budget FY16-FY20

Direct Labor & Fringe Benefits		FY16 ENC	FY17	FY18	FY19	FY20	Assumptions
5311	Leidos Labor						Includes project IDs.
1.0	Fringe						
Subtotal-Direct Labor & Fringe Benefits		\$ -	\$ -	\$ -	\$ -	\$ -	
Materials & Supplies							55% decrease from 16-17 based on # of visits
5420	Occupational Clothing	\$ 5,000	\$ 2,250	\$ -	\$ -	\$ -	
5430	Biologicals	70,000	31,500				
5440	Controlled Materials						
5450	Industrial Supplies	10,000	4,500				
5453	Tools&Test Devices						
5455	Cleaning Supplies	5,000	2,250				
5460	Lab Supplies	90,000	40,500				
5470	Office Supplies	15,000	6,750				
5472	Freight	141,941	33,542				
5473	Telephone/wireless						
5476	Dues						
5477	Books						
5480	Computer Hardware	5,000	2,250				
5481	Computer Software						
Subtotal-Materials & Supplies		\$ 341,941	\$ 123,542	\$ -	\$ -	\$ -	
Other Direct Costs							
5511	Foreign Travel						
5512	Scientific Travel						
5513	Administrative Travel						
5514	Training						
5515	Recruitment						
5516	Relocation Expenses						
5519	International Health Insurance						
5520	FCRF Seminars						
5550	Registration Fees						
5531	Direct Labor Overtime Premium						
5731	Postage						
5721	Vehicle Parts						
5735	Management Support Allocation						
5760	Service Maintenance Agreements						
5762	Software Support						
5764	Relocation of Equipment						
5570	Consultants						
5780	Research Support Services	1,274,908	466,528	187,500			
5790	Admin Support Services	14,700					
5875	Service-Interco Workorder						
5883	Non-SBA Funded						
6450	WH Industrial Supplies						
6460	WH Lab Supplies						
6470	WH Office Supplies						
Subtotal-ODC		\$ 1,289,608	\$ 466,528	\$ 187,500	\$ -	\$ -	
Capital Equipment							KICE + Ace Alera
5610	Capital Equipment	\$ 114,000	\$ 51,300	\$ -	\$ -	\$ -	
Subtotal-Capital Equipment		\$ 114,000	\$ 51,300	\$ -	\$ -	\$ -	
Indirect Costs							
300	Materials, Equip & Subs	3.30%	\$ 57,603	\$ 21,614	\$ 6,450	\$ -	
400	General OH	29.08%					
410	A/C OH	10.11%					
500	G&A	1.04%	18,753	6,961	2,036		
Subtotal-Indirect Costs			\$ 76,356	\$ 28,576	\$ 8,486	\$ -	
SUBTOTAL VARIABLE COSTS			\$ 1,821,905	\$ 669,946	\$ 195,986	\$ -	\$ 2,687,837
Fixed Costs							
	Fixed Cost A location		\$ 1,085,799	\$ 430,851	\$ 165,674	\$ -	
Subtotal-Fixed Costs			\$ 1,085,799	\$ 430,851	\$ 165,674	\$ -	
TOTAL VARIABLE AND FIXED COSTS			\$ 2,907,704	\$ 1,100,797	\$ 361,660	\$ -	
Overhead Rates			FY16	FY17	FY18	FY19	FY20
Fringe - applied to Direct Labor			49.62%	49.55%	49.49%	49.38%	49.29%
MES - applied to Total MES			3.30%	3.37%	3.44%	3.51%	3.59%
General OH - applied to Direct Labor			29.08%	28.79%	28.50%	28.21%	27.94%
App ed/Clinica OH - applied to Direct Labor supported by ADRD or			10.11%	10.09%	10.08%	10.06%	10.04%
G&A - applied Total Direct Costs + Fringe + M&S + All OH			1.04%	1.05%	1.05%	1.05%	1.06%

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Leidos Subcontractor and Consultant Costs

ON IDIQ T014								
5780	Research Support	IDIQ Contract No.	EAC FY16	FY17	FY18	FY19	FY20	Notes
Non responsive								
Um nn Prev IV - G ead		TBD	187,500	375,000	187,500	-	-	Per IGCE
Non-responsive								
			FY16	FY17	FY18	FY19	FY20	Notes
Non-responsive								
Prev 4 - Liberia			1,274,908	466,528	187,500	-	-	
Non-responsive								

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Freight Allocation

Study	FY16	FY17	FY18	FY19	FY20
Non-responsive					

Prev 4 Liberia	\$	314,000	\$	141,300	\$	-	\$	-	\$	-
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Non-responsive

Prev	Visits						
	FY15	FY16	FY17	FY18	FY19	FY20	Total Visits
Non-responsive							
4	-	660	300	-			960
Non-responsive							JFK

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Leidos Non-Severable Ebola

Core Costs/Special Projects	FY15	FY16	FY17	FY18	FY19 EAC	FY20	Total
Non-responsive							
PREVAIL IV - Liberia	-	425,132	144,094	-	-	-	569,226
PREVAIL IV - Guinea	-	-	-	-	-	-	-

Non-responsive

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program

EAC Projections / Additional Funding Requirements IDIQ TO33

Expenses through August 30, 2019.

Non responsive

Leidos Non Severable Ebola

Core Costs/Special Projects	FY16	FY17	FY18	FY19 EAC	FY20	FY21	Total
Non-responsive							
Incremental Cost Per PREVAIL Study							
PREVAIL IV - Liberia	-	586,380	421,969	105,549	50,000	-	1,163,898
PREVAIL IV - Guinea	-	93,064	16,421	365	-	-	109,850
Non-responsive							

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program

EAC Projections / Additional Funding Requirements IDIQ TO43

Expenses through August 30, 2019: Non responsive

Leidos Non-Severable Ebola

Core Costs/Special Projects	FY17	FY18	FY19 EAC	FY20	FY21	FY22	Total
Non-responsive							
PREVAIL IV - Guinea	-	1,216,016	162,787	-	-	-	1,378,803
MCM RCT - DRC (To TO59)		8,133	8,641,452	3,462,677	-	-	12,112,262
Non-responsive							

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO59
Expenses through August 30, 2019
Leidos Non-Severable Ebola

Base Period							Base/Options Tracking	
	FY19 EAC	FY20	FY21	FY22	FY23	Total	Budget	Balance
Non-responsive								
Milestone 2 - Existing Studies (DRC MCM-RCT)	-	6,540,506	-	-	-	6,540,506	8,238,055	1,697,549
Non-responsive								

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Leidos Biomed Non-Severable Funding

Ebola Funding for West Africa & the DRC*	Actual FY14	Actual FY15	Actual FY16	Actual FY17	Actual FY18	Projection FY19	Projection FY20	Projection FY21	Projection FY22	Projection FY23	Projection FY24	Total
Non-responsive												
PREVAIL IV - Liberia	-	-	425,132	730,474	421,969	105,549	-	-	-	-	-	1,683,124
PREVAIL IV - Guinea				93,064	1,232,437	163,152						1,488,653
Non-responsive												
MCMRCI in DRC	-	-	-	-	8,133	8,656,267	10,003,182	-	-	-	-	18,667,582
Non-responsive												
Non-responsive												

*No US Funding available past FY22

EXPIRES AT THE END OF FY22: 6,900,000

Non-responsive

Leidos Non-Severable Ebola

Core Costs/Special Projects

Core Costs/Special Projects	FY15	FY16	FY17	FY18	FY19 EAC	FY20	Total
Non-responsive							
PREVAIL IV - Liberia	-	425,132	144,094	-	-	-	569,226
PREVAIL IV - Guinea	-	-	-	-	-	-	-
Non-responsive							
Non-responsive							\$ 402,480

Leidos Biomedical Research, Inc
 Clinical Monitoring Research Program
 EAC Projections / Additional Funding Requirements IDIQ TO33
 Expenses through August 30, 2019:
 Leidos Non-Severable Ebola

Non responsive

Non responsive

Incremental Cost Per PREVAIL Study							
PREVAIL IV - Liberia	-	586,380	421,969	105,549	-	-	1,113,898
PREVAIL IV - Guinea	-	93,064	16,421	365	-	-	109,850

Non-responsive

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program

EAC Projections / Additional Funding Requirements IDIQ TO43

Expenses through August 30, 2019:

Non responsive

Leidos Non-Severable Ebola

Non-responsive

PREVAIL IV - Guinea	-	1,216,016	162,787	-	-	-	1,378,803
MCM RCT - DRC (To TO59)		8,133	8,641,452	3,462,677	-	-	12,112,262

Non-responsive

Non-responsive

6,800,000

Non-responsive

Non-responsive	
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Non-responsive

\$	6,800,000
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Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO59
Expenses through August 30, 2019
Leidos Non-Severable Ebola

Non-responsive

Base Period	FY19 EAC	FY20	FY21	FY22	FY23	Total	Base/Options Tracking	
							Budget	Balance
Non-responsive								
Milestone 2 - Existing Studies (DRC MCM-RCT)	-	6,540,506	-	-	-	6,540,506	8,238,055	1,697,549
Non-responsive								
Non-responsive						\$ 17,680,783		

Non-responsive

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Additional Requirements Not Included in Current FY16 IDIQ Expenses:

Not included in the EAC

Requirement	Est. Amount Outstanding	Notes:
Non-responsive		
7.) PREVAIL IV		AMBL lab costs
8.)		
9.)		
10.)		
11.)		
12.)		
Total Outstanding \$	2,500,000.00	



Leidos Biomedical Research, Inc.

PREVAIL Finance Discussion

November 7, 2017

Agenda

Purpose This presentation outlines spend to date, spend plans against budgets, and the steps to be taken for fiscally responsible actions to approve new science and the process for managing changes to task orders. This discussion pertains to YT15-011NS, Task Order 33, Task Order 14, and Task Order 43.

Review of Actuals Versus Budgets

Review of LBR Staffing, Travel and Other Expenses

Review of Subcontracts – TMG, LCP, UMN, InCadence, ABML

Review of IRF Spending

Conference Support

Unanticipated Expenses

Authority Matrix – New Science Proposals

TO43 Budget

TO43 Change Management Process

Next Steps

Proposed Cost Savings Measures

Review of Actuals Versus Budgets

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Actuals Versus Budget Task Order 14

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
Status of IDIQ TO14

Leidos Non-Severable Ebola

					FY18	
Non-responsive	FY15	FY16	FY17 EAC	2018 Expenses	Encumbrances	Total
Non-responsive						
Incremental Cost Per Study						
Non-responsive						
PREVAIL IV - Liberia	-	569,150	3,164	-	-	572,313
PREVAIL IV - Guinea						-
Non-responsive						

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Actuals Versus Budget Task Order 33

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
Status of IDIQ TO33

Leidos Non-Severable Ebola

	FY18				
Non-responsive	FY16	FY17	FY18 Expenses	Encumbrances	Total
Non-responsive					

Incremental Cost Per PREVAIL Study

Non-responsive					
PREVAIL IV - Liberia	5,381	621,592	1,791	53	628,817
PREVAIL IV - Guinea	-	100,877	3	-	100,880

Non-responsive					
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Summary Actuals Versus Budget (YT 15-011NS, TO14, TO33)

Leidos Non-Severable Ebola

						FY18	
Core Costs	FY14	FY15	FY16	FY17	Encumbrances	Total	
Non-responsive							

Incremental Cost Per PREVAIL Study

Non-responsive							
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PREVAIL IV - Liberia	-	-	574,530	624,756	1,845	1,201,131
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Non-responsive							
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Task Order 43 Proposed Budget

Leidos Biomedical Research, Inc.

Clinical Monitoring Research Program

Status of IDIQ TO43

Leidos Non-Severable Ebola

Core Costs	FY17	FY18 EAC	FY19	FY20	FY21	FY21	Total
Non-responsive							

Incremental Cost Per PREVAIL Study

PREVAIL IV - Guinea	-	1,195,247	22,093	-	-	-	1,217,340
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Review of Subcontracts - TMG, LCP, UMN, InCadence, ABML

Subcontracts Overview

EBOLA SUBCONTRACTS

Subcontractor	Study	PO#	TPM/RC	Period of Performance	Funded Amount	Remaining Funds	Funded Through	Invoice Status	Burn Rate	# Months Funding Remaining	Month Funding Required	Funding Notes	Task Order
Non-responsive													
University of Minnesota	PREVALENT Guinea	16X054Q5	Sara/Eileen	8/13/2016 - 12/31/2017	464,820	227	10/31/2017	Aug 17	37,061	0.01	Aug 17	POP extended as the study has been extended due to slow enrollment. Mod to request budget for P4 Guinea	TO33
Non-responsive													

Last Updated: 11/1/2017

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Review of IRF Costs

IRF Purchases for FY15, FY16 and FY17

Country	Clinical Trial	FY2015	FY2016	FY2017	FY2018-Q1	Grand Total
Guinea	Non-responsive					
	PREVAIL IV	\$ -	-	-	15,482	\$ 15,482
Guinea Total	Non-responsive					
Liberia						
	PREVAIL III, IV, VI	\$ -	-	-	77	\$ 77
	PREVAIL IV	\$ -	60,785	659	-	\$ 61,444
	Non-responsive					
Liberia Total						
U.S.A.						
	PREVAIL IV	\$ -	-	6,180	6,865	\$ 13,045
	Non responsive					
Non-responsive						

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Unanticipated Expenses

Unanticipated Expenses

- Examples to include PREVAIL IV rural recruitments

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Task Order 43 Budgeted Scope

The budget presented reflects our complete and current estimate of the cost required to complete the SOW and deliver the deliverables. This budget reflects the milestones for this work. The milestones will occur concurrently. Any new studies will be undertaken only after discussion with NIAID DCR regarding the requirements, followed by an internal assessment of resources needed for the new study and the resources remaining on this task order. Completion of Specific Pre-existing Studies Facilitate conduct, follow-up and close-out of PREVAIL IV in Guinea,

Non-responsive

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Task Order 43 Proposed Budget

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
Status of IDIQ TO43

Leidos Non-Severable Ebola

Core Costs	FY17	FY18 EAC	FY19	FY20	FY21	FY21	Total
Non-responsive							

Incremental Cost Per PREVAIL Study

PREVAIL IV - Guinea	- 1,195,247	22,093	-	-	- 1,217,340
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Next Steps

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7	Project/Activities																																																																																																			
8																																																																																																				
58	Labor/Operations Support																																																																																																			
63	Overarching Operational Support (Leidos labor and contracts)																								Leidos Labor																																																																											
64																									Contract: TMG Overarching																																																																											
65		OTS 15-011NS										TO14										TO33																		TO43																																																												
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74		OTS 15-011NS																														TO34																																																																				
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86	UMN PREVAIL IV (Q5)																						Option year to be executed																																																																													
87													TO14					TO33																																																																																		
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112																										15-011NS - March 2018 (blue)																																																																										
113																										TO14 - June 2019 (orange)																																																																										
114																										TO33 - November 2018 (gray)																																																																										
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AWARD/CONTRACT		1 THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING		PAGE OF PAGES 1 10	
2 CONTRACT (Proc. Inst. Ident.) NO. 75N91019D00024/75N91020F00010				3 EFFECTIVE DATE See Block 20C		4 REQUISITION/PURCHASE REQUEST/PROJECT NO. 5683381	
5 ISSUED BY National Institutes of Health National Cancer Institute Bldg 1050 Frederick, MD 21702		CODE NCI-BLDG 427		6 ADMINISTERED BY (If other than Item 5) National Institutes of Health National Cancer Institute Bethesda, MD 20892-7511		CODE NCI	
7 NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code) LEIDOS BIOMEDICAL RESEARCH, INC.:1107088 P.O. BOX B FREDERICK MD 217029242				8 DELIVERY FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)			
				9 DISCOUNT FOR PROMPT PAYMENT			
				10 SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN			
CODE		FACILITY CODE		ITEM			
11 SHIP TO/MARK FOR 5601 Fishers Lane Rockville, MD 208 5601 Fishers Lane Rockville MD 20852		CODE 5601 FL		12 PAYMENT WILL BE MADE BY Approved By, NCI Branch D Invoices Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500		CODE NCI INV-BR-D	
13 AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: 10 U.S.C. 2304 (a) () <input checked="" type="checkbox"/> 41 U.S.C. 3304 (a) (3)				14 ACCOUNTING AND APPROPRIATION DATA See Schedule			
15A. ITEM NO	15B. SUPPLIES/SERVICES			15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Continued							
15G. TOTAL AMOUNT OF CONTRACT						\$6,680,834.00	
16. TABLE OF CONTENTS							
(X)	SEC	DESCRIPTION	PAGE(S)	(X)	SEC	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	6
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	4	X	J	LIST OF ATTACHMENTS	10
X	D	PACKAGING AND MARKING	4	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	4		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	4		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	5		M	EVALUATION FACTORS FOR AWARD	
X	H	SPECIAL CONTRACT REQUIREMENTS	6				
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17 X CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary (Block 18 should be checked only when awarding a sealed-bid contract.)			
19A. NAME AND TITLE OF SIGNER (Type or print) Connie Suders, Principal Contracts Administrator				20A. NAME OF CONTRACTING OFFICER SCOTT P. KEASEY			
19B. NAME OF CONTRACTOR Connie E. Suders BY -S (Affiliate) (Signature of person authorized to sign)			19C. DATE SIGNED April 01, 2020	20B. UNITED STATES OF AMERICA Scott P. Keasey -S (Signature of the Contracting Officer)			20C. DATE SIGNED Date: 2020.04.01 19:15:12 -04'00'

CONTINUATION SHEET

REFERENCE NO OF DOCUMENT BEING CONTINUED
75N91019D00024/75N91020F00010PAGE OF
2 10

NAME OF OFFEROR OR CONTRACTOR

LEIDOS BIOMEDICAL RESEARCH, INC.:1107088

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	<p>Period of Performance: 04/03/2020 to 04/02/2025</p> <p>75N91019D00024;75N91020F00010;600.010.77.01;NIAID-DMID-DMID;CVD Preparedness and Response Supplemental Appropriations Act 2020 Delivery To: 5601 FL Product/Service Code: M1HA Product/Service Description: OPERATION OF GOVERNMENT-OWNED CONTRACTOR-OPERATED (GOCO) R&D FACILITIES</p> <p>Project Data: 150809.2020.400.COVID19.THERP.HNMS NIAID DMID DIV MICROBIOLOGY & INFECTIOUS DISEASES.25505 RESEARCH AND DEVELOPMENT.03/19/2020 Accounting Info: 08019720205DAD.2020.01.M100.HNM1000000C.E.00066.40 6.NCOV.25505.61000001.9999.9999.9999 Funded: \$6,680,834.00</p>				6,680,834.00

In addition to all applicable terms and conditions of the Base Contract 75N91019D00024, the following ARTICLES are also applicable to this task order.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

NIAID DMID: COVID-19 Remdesivir Study

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

- a. The estimated cost of this contract is \$TBD.
- b. The fixed fee for this contract is \$TBD. The fixed fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of The NCI FFRDC Contract.
- c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is \$TBD.

ARTICLE B.3. ADVANCE UNDERSTANDINGS

- a. Task Order Number Designation
On all correspondence submitted under this Task Order, the Contractor agrees to clearly identify the Task Order and contract numbers that appear on the face page of the contract as follows:

Task Order No.: 75N91020F00010
Contract No.: 75N91019D00024
- b. Advance Payment
An advance payment in the amount of \$TBD has been negotiated for this task order. The entirety of the advance payment provided from this order shall be repaid against this order.
- c. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

Other provisions of this task order notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

- a. Subcontracts
A Subcontracting ceiling of \$TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to: 1) exceed this ceiling or 2) enter into foreign or legal services subcontracts.
- b. Consultants
A Consultants ceiling of \$TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required for all consultant agreements and modifications to consultant agreements related to cost or scope.
- c. Accountable Government Property (Capitalized Equipment)
An Accountable Government Property (Capitalized Equipment) ceiling of \$TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to exceed this ceiling.
- d. Travel

A Travel ceiling of \$ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to: 1) to exceed this ceiling or 2) for all foreign travel. All travel costs exceeding those authorized under the Federal Travel Regulations (FTR) must be justified in writing to the Contracting Officer for Contracting Officer Authorization.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, dated TBD, set forth in SECTION J-List of Attachments, attached hereto and made a part of this Task Order.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973.

Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Making Files Accessible."

Reporting requirements TBD.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this Task Order other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of materials and services to be provided.
- b. Inspection and acceptance will be performed as identified in the NCI FFRDC Bridge Contract for contract-wide requirements and per task order for specific task order requirements.
Inspection and acceptance for Reporting Requirements will be performed at (via) unless otherwise specified in the Task Order:

National Cancer Institute at Frederick
FFRDC Contract Administration System
<https://fcas.nci.nih.gov>

The Government reserves the right to an Inspection period of 30 calendar days. The receiving report constitutes acceptance. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this task order is April 3, 2020 through April 02, 2025.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final task order shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this task order and upon delivery and acceptance by

the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this task order will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Item	Task Order Article	Description	Delivery Schedule
TBD	TBD	TBD	TBD

- b. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.
Delivered to the Contracting Officer and COR through the FFRDC Contract Administration System (FCAS)	TBD

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Seema Nayak

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this task order; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this task order; (5) otherwise change any terms and conditions of this task order; or (6) sign written licensing agreements.

The Government may unilaterally change its COR designation.

ARTICLE G.2. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all task orders.

TBD

Primary Program Manager

ARTICLE G.3. INVOICE SUBMISSION

In addition to the requirements specified in the base contract 75N91019D00024 and FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

- a. The Contract Title is: The NCI FFRDC Bridge Contract
- b. The Task Order Title is: NIAID DMID: COVID-19 Remdesivir Study
- c. Task Order Line Items are as follows:

PRISM Line Item #	Line Item Description/Project ID	IC	CAN (with Fiscal Year)	CAN Label	Amount	End Date of Funds Availability
1	75N91020F00010; 75N91019D00024, 600 010 77 01; NIAID- DMID-DMID; CVD Preparedness and Response Supplemental Appropriations Act 2020	NIAID	0-8044363	Appropriated	\$6,680,834.00	04/02/2025

SECTION H - ADDITIONAL CONTRACT CLAUSES

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH & DEVELOPMENT CONTRACT

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

- a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES
 1. **Alternate I** (April 1984) of FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), is hereby deleted in its entirety and **Alternate V** (April 1984), is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

- a. **FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES**

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCEMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning them to the Contracting Officer not later than April 3, 2020, 3:00PM EST. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding \$6,680,834.00 dollars.

(b) The maximum amount for which the Government shall be liable if this contract is terminated is \$6,680,834.00 dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Cost Plus Fixed Fee definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Cost Plus Fixed Fee proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is:

Definitization Schedule

a. Statement of Work Review 3-26-2020 - 4-01-2020

b. Issuance of Letter Contract 4-03-2020

c. Letter Contract Post Award Kick Off meeting 4-08-2020

d. Contractor Price Proposal Submittal 5-06-2020

e. POTQ/Technical Review 5-06-2020 - 5-15-2020

f. Negotiations Start 5-18-2020 - 5-22-2020

g. Request Certificate of Current Cost and/or Pricing 5-25-2020

h. Definitization of Letter Contract 5-25-2020 - 6-05-2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

4. FAR 52.216-26 - PAYMENTS OF ALLOWABLE COSTS BEFORE DEFINITIZATION (DEC 2002)

(a) Reimbursement rate. Pending the placing of the definitive contract referred to in this letter contract, the Government will promptly reimburse the Contractor for all allowable costs under this contract at the following rates:

(1) One hundred percent of approved costs representing financing payments to subcontractors under fixed-price subcontracts, provided that the Government's payments to the Contractor will not exceed 80 percent of the allowable costs of those subcontractors.

(2) One hundred percent of approved costs representing cost-reimbursement subcontracts; provided, that the Government's payments to the Contractor shall not exceed 85 percent of the allowable costs of those subcontractors.

(3) Eighty-five percent of all other approved costs.

(b) Limitation of reimbursement. To determine the amounts payable to the Contractor under this letter contract, the Contracting Officer shall determine allowable costs in accordance with the applicable cost principles in part 31 of the Federal Acquisition Regulation (FAR). The total reimbursement made under this paragraph shall not exceed 85 percent of the maximum amount of the Government's liability, as stated in this contract.

(c) Invoicing. Payments shall be made promptly to the Contractor when requested as work progresses, but (except for small business concerns) not more often than every 2 weeks, in amounts approved by the Contracting Officer. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost incurred by the Contractor in the performance of this contract.

(d) Allowable costs. For the purpose of determining allowable costs, the term "costs" includes-

(1) Those recorded costs that result, at the time of the request for reimbursement, from payment by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(2) When the Contractor is not delinquent in payment of costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for-

(i) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made-

(A) In accordance with the terms and conditions of a subcontract or invoice; and

(B) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(ii) Materials issued from the Contractor's stores inventory and placed in the production process for use on the contract;

(iii) Direct labor;

(iv) Direct travel;

(v) Other direct in-house costs; and

(vi) Properly allocable and allowable indirect costs as shown on the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(3) The amount of financing payments that the Contractor has paid by cash, check, or other forms of payment to subcontractors.

(e) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(f) Audit. At any time before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of costs audited. Any payment may be-

(1) Reduced by any amounts found by the Contracting Officer not to constitute allowable costs; or

(2) Adjusted for overpayments or underpayments made on preceding invoices or vouchers.

5. ---**Alternate I of 52.222-26** with the following fill in: "The following terms of this clause are waived for this contract: subparagraph (c)(2), (c)(3), (c)(4), (c)(5)(ii), (c)(6), (c)(8), and the phrase "on-site compliance evaluations and" in (c)(9)."

6. ---**Alternate I of 52.222-35** with the following fill in: "The following terms of this clause are waived for this contract: in subparagraph (b), the phrase "and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans"; additionally, in subparagraph (b), the phrase "requirements of the equal opportunity clause at 41CFR 60-300.5(a)" shall be interpreted to exclude in full paragraphs 2-7, 9-10, and 12 of 41 CFR 60-300.5(a), and the phrase "take affirmative action to employ, advance in employment and otherwise" from paragraph 1 of 41 CFR 60-300.5(a)."

7. ---**Alternate I of 52.222-36** with the following fill in: "The following terms of this clause are waived for this contract: in subparagraph (a), the phrase "and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities"; additionally, in subparagraph (a), the phrase "requirements of the equal opportunity clause at 41 CFR 60-741.5(a)" shall be interpreted to exclude in full paragraphs 4-5 and 7 of 41 CFR 60-741.5(a), and the phrase "take affirmative action to employ and advance in employment individuals with disabilities, and to "from paragraph 1 of 41 CFR 60-741.5(a)."

**PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER
ATTACHMENTS SECTION J LIST OF ATTACHMENTS**

1. Statement of Work

DMID: COVID19 Remdesivir Study

National Institute of Allergy and Infectious Diseases

Division of Microbiology and Infectious Diseases

Non-Severable Task Order

COVID19 Trial

March 2020

DMID: COVID19 Remdesivir Study

1. INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID) strives to understand, treat, and ultimately prevent the myriad of infectious, immunologic, and allergic diseases threatening the health of millions of people in the United States and around the world. Against a background of established infections, epidemics of new and old infectious diseases periodically emerge. This threat has been increasingly recognized over the last decade. Emerging/re-emerging and related respiratory viruses causing disease, such as SARS, influenza, and MERS-CoV are of particular concern given their significant morbidity and potential for rapid geographic spread. This objective supports the overall goal to better understand the diseases and therapeutic options and to improve medical outcomes for patients afflicted with the emerging and re-emerging and related respiratory viruses.

1.1 Background

The National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID), rapidly deploys resources to meet the external demands placed on NIAID to facilitate the conduct of time sensitive, high priority, global, collaborative clinical research critical to the mission of the NIAID and advancement of the National Institutes of Health (NIH) and Department of Health & Human Services (DHHS) Global Health Agendas. Fulfillment of this mission requires DMID to have the capacity to expeditiously support collaborative clinical research and conduct clinical trials both domestically and internationally.

In December 2019, the Wuhan Municipal Health Committee identified an outbreak of viral pneumonia cases of unknown cause. Coronavirus RNA was quickly identified in some of these patients. This novel coronavirus has been designated SARS-CoV-2, and the disease caused by this virus has been designated COVID-19. There were 59 confirmed cases on January 5, 2020, 278 cases on January 20, 2118 cases on January 26, rising to more than 64,000 confirmed cases and 1300 deaths as of February 14, 2020 according to various international health reporting agencies. Currently there are no approved therapeutic or prophylactic agents available for coronaviruses.

The objective of this COVID Task Order supports NIAID's goal to better understand the Coronavirus.

DMID is requesting the services of Leidos Biomedical Research, Inc. (LBR) to initiate the management, oversight, and conduct of the NIAID DMID clinical trial titled "A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19" ("Trial"). This study is an adaptive, randomized, double-blind, placebo-controlled trial to

DMID: COVID19 Remdesivir Study

evaluate the safety and efficacy of novel therapeutic agents in hospitalized adult patients diagnosed with COVID-19. The study is a multicenter trial that will be conducted in up to 60 sites globally. The study will compare different investigational therapeutic agents to a placebo. There will be interim monitoring to introduce new arms and allow early stopping for futility, efficacy, or safety. If one therapy proves to be efficacious, this treatment will then become the control arm for comparison(s) with new experimental treatment(s). Because of the possibility that background standards of supportive care may evolve/improve over time as more is learned about successful management of COVID-19, comparisons of safety and efficacy will be based on data from concurrently randomized participants. An independent data and safety monitoring board (DSMB) will actively monitor interim data to make recommendations about early study closure or changes to study arms.

There is no benefit to NIAID until the completion and closeout of the study contemplated hereunder.

Business Assumptions are outlined under Appendix A.

2. Statement of Work

Under this Task Order, LBR shall provide the full range of services required to support DMID in conducting the Trial contemplated hereunder including, but not necessarily limited to, those listed in this Section 2.

2.1 Technical Support and Administrative Management Services

DMID requires LBR to provide the broad range of technical support and administrative management services and program- dedicated research support required to conduct the Trial domestically and internationally as requested.

LBR will establish and maintain a Coordinating Center (CC) to support the Trial with a primary base of operations co-located with NIAID at 5601 Fishers Lane, Rockville, MD.

While not intended to be an exhaustive list of the CC responsibilities, the CC will:

- A. Assist the sites in developing, implementing, and monitoring the scientific agenda.
- B. Develop agenda and provide logistical support for trial related meetings.
- C. Coordinate the development, dissemination, implementation, and update of Manual of Operations and other protocol related documents.
- D. Coordinate, develop and disseminate protocols and amendments.
- E. Provide translation support of these documents as needed.
- F. Coordinate and administer research activities including, but not limited to the following:
 - Support the laboratories, and protocol teams;
 - Maintain administrative records and archives;

DMID: COVID19 Remdesivir Study

- Coordinate trial related workshops, meetings and conference calls;
 - Prepare administrative and scientific reports.
- G. Develop and maintain a web-based system for dissemination of information.
- H. Provide regulatory guidance to investigators and coordinate training of staff at trial sites
- I. Assure adherence to internationally mandated ethical and Good Clinical Practice requirements regarding conduct of research involving human subjects.
- J. Coordinate and track the publication of Network study results.
- K. Coordinate and support preparation of manuscript and scientific presentations.
- L. Coordinate and administer training activities needed for the trial.
- M. Support sites during trial conduct to include maintaining a 24/7 help line / help desk to rapidly respond to inquiries about the study from participating sites.
- N. Gather evaluation data to evaluate site performance.
- O. Provide pharmacy guidance and oversight to sites and protocol teams including importation of study drugs.
- P. Coordinate and provide procurement support for sites and laboratories.
- Q. Provide Information Technology guidance to sites to enhance wide communication and data transfer activities.
- R. Track enrollment to studies .
- S. Provide guidance to sites on interfacing with the NIAID Statistical and Data Coordinating Center (SDCC) and Clinical Agent Repositories (CAR) for the study.
- T. Coordinate and support the development of laboratory capacity if needed.
- U. Support the distribution and shipment of specimens.
- V. Coordinate documents collection from sites to the Sponsor NIAID.
- W. Support the sites submission to regulatory authorities .
- X. Perform other duties as required and/or requested by NIAID to ensure optimal coordination of the multi-site, multi-county COVID19 clinical trial.

In DMID's opinion FHI360 is a vendor that is well suited to perform the CC requirements under this YT given their expansive operations domestically and globally; proven track record implementing complex clinical research protocol; and having served as the Network Coordinating Center for NIAID DCR's Special Project – SEAICRN as a subcontractor under LBR.

2.2 Conduct Broad Range of Research

DMID requires LBR to provide other services and additional scientific disciplines as required to facilitate the management and conduct of the Trial contemplated hereunder.

DMID is requesting that LBR furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to implement the Trial, while ensuring that tasks are conducted in accordance with all applicable and current country, federal, state, and local laws, codes, ordinances and regulations.

DMID: COVID19 Remdesivir Study

While not intended to be an exhaustive list, requirements include:

- A. Administrative, Project Management and Overall Support for all Clinical Site Activities
 - 1. Manage and provide oversight of the Task Order and Subcontractor.
 - 2. Maintain frequent communications and updates with the COR on the status of the Task Order Activities
- B. Clinical Site Identification, Site Readiness and Start-up Activities Prior to Protocol Implementation
The Contractor shall implement, conduct, complete and provide oversight of the clinical study protocol at up to 60 sites. It is anticipated sites are identified mainly from NIAID, but also from contractor, or other collaborators.

For sites the contractor (directly or through operations center) should:

- 1. Distribute and collect a clinical site assessment utilizing the NIAID Site Questionnaire (Attachment A).
- 2. Participate in a Site Assessment and/or Site Initiation Visit(s) in conjunction with the NIAID Monitoring Contractor in person or by teleconference. Site Initiation may be done via teleconference or in person, at the sponsors discretion.
- 3. Assist the site in obtaining initial IRB/IEC, local regulatory authority (as applicable), and other local/institutional approvals as needed, including amendments.
- 4. Assist in the preparation of regulatory documentation.
- 5. Negotiate and execute all site budgets with Contract Officer approval.
- 6. Manage clinical sites in accordance with the Protocol and Manual of Procedures.
- 7. Support, if requested, monitoring or audits of clinical trial sites and vendors.
- 8. Manage investigator site payments, vendor payments, and other indirect direct costs per contract and budget.

The sites should

- 1. Perform all clinical study procedures as described in the Protocol, the Manual of Procedures, Quality Management Plan, Pharmacy Manual and relevant Standard Operating Procedures.
- 2. Perform laboratory analysis of samples as specified in the Protocol and in accordance with cGLP and cGCP regulations and in compliance with domestic and non-domestic laws and regulations.
- 3. Recruit and retain the study population as defined in the Protocol.
- 4. Identify potential problems associated with conducting this trial including but not limited to those related to recruitment, retention and implement risk mitigation strategies.
- 5. Maintain study records (Source Documentation Standards)
 - Documentation of source data should be in compliance with federal, state, local, institutional and international clinical research policies, and consistent with the NIAID NIAID Source Documentation Standards.
 - In carrying out the Protocol, the Contractor is required to maintain regulatory records in accordance with federal, state, local, institutional, and international clinical research policies, and consistent with the NIAID NIAID Regulatory File Document Guidelines).
- 6. Data Management and Quality Control

DMID: COVID19 Remdesivir Study

- The Contractor shall collect study data and transfer (direct transfer, completion of CRF, etc. as appropriate) all clinical and laboratory study data to the NIAID SDCC system within seventy-two (72) hours of study visit procedures or activity as defined in the Manual of Procedures, in accordance with the Protocol.
 - Participate in data cleaning activities with the site and the SDCC.
 - 7. Study Agents
 - Receive, inventory, store, and dispose/return (unused study agent) study product as specified by NIAID.
 - 8. Regulatory Requirements
 - Maintain IRB/IEC approval, in addition to local regulatory authority approvals, and other local/institutional approvals as needed for amendments and other clinical research modifications.
 - Provide IRB approval documentation per NIAID-CROMS
 - 9. Safety Reporting
 - Report SAEs in the timeframe specified in the protocol.
 - Provide safety follow-up information to NIAID-CROMS as referenced in the Protocol.
- C. Clinical Site Training
1. Assist Clinical Sites with Protocol Specific Training to include training documents posted on the NIAID SDCC Contractors website and ensure site staff have completed the appropriate training for their roles.
 2. Provide GCP and/or HSP Training as needed to Clinical Site Staff in accordance with NIH Requirements.
 3. Assist sites in navigating other study specific training for data management and study product ordering.
- D. Protocol Implementation, Conduct, Completion, Analysis and Oversight
1. Protocol Specific Meeting and Teleconference Support.
 2. Provide for and participate in Protocol specific meeting and teleconference support.
 3. Prepare and distribute meeting and teleconference related materials at least 1 day in advance of all teleconferences. Prepare meeting or teleconferences minutes within 5 calendar days of the meeting or teleconference.
 4. Participate in close-out related meetings/teleconferences for the sites and the clinical study. Participate with the site and the SDCC in all data cleaning activities.
 5. In coordination with the Protocol Team, prepare a manuscript of the primary study results suitable for submission to a peer-reviewed scientific journal.
 6. Arrange and participate in an End of Study Results Dissemination Face-To-Face Meeting.
- E. Virology testing
1. Identify, manage, and provide payment for a laboratory capable of processing the virologic endpoints of the protocol:
 - Qualitative and quantitative PCR for SARS-CoV-2 in OP swab
 - Qualitative and quantitative PCR for SARS-CoV-2 in blood

DMID: COVID19 Remdesivir Study

At the conclusion of the program, a consolidated final report shall be submitted to NIAID DMID summarizing accomplishments, outcomes, and impact on the overall research initiative to improve medical outcomes for patients.

Appendix A

Business Assumptions

A. Study

1. Initial sample size is 440 subjects (includes 10% lost to follow-up). Additional enrollment may be required. This number may be increased up to 709 based upon the true odds ratio or it may also be increased if additional therapeutic arms are added.

B. Coordinating Center

2. Ten FTE equivalents (five 100% FTE, and others with split responsibilities) - some co-located within NIAID at 5601 Fishers Lane, Rockville, MD and some located at an international location.
3. Travel – (2) persons traveling to each site two times per year

C. Sites

1. Up to 100 sites based domestically and internationally, of which the Contractor may be asked to fund up to 70 sites
2. International locations may include sites in:
 - 1) South Korea
 - 2) Singapore
 - 3) Thailand
 - 4) Japan
 - 5) Italy
 - 6) United Kingdom
 - 7) Other countries may be added

3. Per Site Reimbursement

- 1) \$10k site initiation fee
- 2) \$20k per subject enrolled
- 3) \$10k per year for site principal investigator and staff time to maintain the study regulatory files, IRB continuing reviews, etc.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1 CONTRACT ID CODE		PAGE OF PAGES	
				1 10	
2 AMENDMENT/MODIFICATION NO		3 EFFECTIVE DATE		4 REQUISITION/PURCHASE REQ NO	
P00001		See Block 16C		5701719	
6 ISSUED BY		CODE		5 PROJECT NO (If applicable)	
National Institutes of Health National Cancer Institute Bldg 1050 Frederick, MD 21702		NCI-BLDG 427		7 ADMINISTERED BY (If other than Item 6) CODE NCI National Institutes of Health National Cancer Institute Bethesda, MD 20892-7511	
8 NAME AND ADDRESS OF CONTRACTOR (No. street, county, State and ZIP Code)		(x)		9A. AMENDMENT OF SOLICITATION NO	
LEIDOS BIOMEDICAL RESEARCH, INC.:1107088 P.O. BOX B FREDERICK MD 217029242				9B DATED (SEE ITEM 11)	
		x		10A. MODIFICATION OF CONTRACT/ORDER NO. 75N91019D00024 75N91020F00010	
				10B DATED (SEE ITEM 13) 04/01/2020	
CODE		FACILITY CODE			

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15 and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) Net Increase: \$10,104,139.00
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF FAR 43.103(a).
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

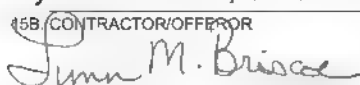
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings including solicitation/contract subject matter where feasible)

The purpose of this modification is to provide supplemental funding in the amount of \$10,104,139 for revisions to the Statement of Work. The total obligated value of this task order increases from \$6,680,834 by \$10,104,139 to \$16,784,973. The total ultimate value of this task order increases from \$6,680,834 by \$10,104,139 to \$16,784,973. This modification also changes the Contracting Officer's Representative (COR). ARTICLE G.1., ARTICLE G.3., ARTICLE I.4., SECTION J., and the Statement of Work are revised.

Period of Performance: 04/03/2020 to 04/02/2025

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) Lynn M. Briscoe, Sr. Contracts Manager		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) SCOTT P. KEASEY	
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)		16B. UNITED STATES OF AMERICA Scott P. Keasey -S (Signature of Contracting Officer)	
15C. DATE SIGNED 05/04/2020		16C. DATE SIGNED Digitally signed by Scott P. Keasey -S Date: 2020.05.04 12:38:59 -04'00'	

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75N91019D00024/75N91020F00010/P00001	PAGE	OF
		2	10

NAME OF OFFEROR OR CONTRACTOR

LEIDOS BIOMEDICAL RESEARCH, INC.:1107088

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Delivery: 04/02/2025 Delivery Location Code: 5601 FL 5601 Fishers Lane Rockville, MD 208 5601 Fishers Lane Rockville MD 20852 US Payment: Approved By, NCI Branch D Invoices Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500 Period of Performance: 04/03/2020 to 04/02/2025 Add Item 2 as follows:				
2	75N91020F00010; 75N91019D00024; 600.010.77.01; NIAID-DMID-DMID; CVD Preparedness and Response Supplemental Appropriations Act 2020 Delivery To: 5601 FL Product/Service Code: M1HA Product/Service Description: OPERATION OF GOVERNMENT-OWNED CONTRACTOR-OPERATED (GOCO) R&D FACILITIES Project Data: 150809.2020.400.COVID19.THERP.HNM5 NIAID DMID DIV MICROBIOLOGY & INFECTIOUS DISEASES.25505 RESEARCH AND DEVELOPMENT.04/29/2020 Accounting Info: 08019720205DAD.2020.01.M100.HNM1000000C.E.00066.40 6.NCOV.25505.61000001.9999.9999.9999 Funded: \$10,104,139.00				10,104,139.00

In addition to all applicable terms and conditions of the Base Contract 75N91019D00024, the following ARTICLES are also applicable to this task order.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

NIAID DMID: COVID-19 Remdesivir Study

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

- a. The estimated cost of this contract is \$TBD.
- b. The fixed fee for this contract is \$TBD. The fixed fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of The NCI FFRDC Contract.
- c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is \$TBD.

ARTICLE B.3. ADVANCE UNDERSTANDINGS

- a. Task Order Number Designation
On all correspondence submitted under this Task Order, the Contractor agrees to clearly identify the Task Order and contract numbers that appear on the face page of the contract as follows:

Task Order No.: 75N91020F00010
Contract No.: 75N91019D00024
- b. Advance Payment
An advance payment in the amount of \$TBD has been negotiated for this task order. The entirety of the advance payment provided from this order shall be repaid against this order.
- c. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

Other provisions of this task order notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

- a. Subcontracts
A Subcontracting ceiling of \$ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to: 1) exceed this ceiling or 2) enter into foreign or legal services subcontracts.
- b. Consultants
A Consultants ceiling of \$ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required for all consultant agreements and modifications to consultant agreements related to cost or scope.
- c. Accountable Government Property (Capitalized Equipment)
An Accountable Government Property (Capitalized Equipment) ceiling of \$ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to exceed this ceiling.
- d. Travel

A Travel ceiling of \$ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to: 1) to exceed this ceiling or 2) for all foreign travel. All travel costs exceeding those authorized under the Federal Travel Regulations (FTR) must be justified in writing to the Contracting Officer for Contracting Officer Authorization.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, dated TBD, set forth in SECTION J-List of Attachments, attached hereto and made a part of this Task Order.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973.

Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Making Files Accessible."

Reporting requirements TBD.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this Task Order other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of materials and services to be provided.
- b. Inspection and acceptance will be performed as identified in the NCI FFRDC Bridge Contract for contract-wide requirements and per task order for specific task order requirements.
Inspection and acceptance for Reporting Requirements will be performed at (via) unless otherwise specified in the Task Order:

National Cancer Institute at Frederick
FFRDC Contract Administration System
<https://fcas.nci.nih.gov>

The Government reserves the right to an Inspection period of 30 calendar days. The receiving report constitutes acceptance. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this task order is April 3, 2020 through April 02, 2025.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final task order shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this task order and upon delivery and acceptance by

the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this task order will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Item	Task Order Article	Description	Delivery Schedule
TBD	TBD	TBD	TBD

- b. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.
Delivered to the Contracting Officer and COR through the FFRDC Contract Administration System (FCAS)	TBD

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Sonia Gales

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this task order; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this task order; (5) otherwise change any terms and conditions of this task order; or (6) sign written licensing agreements.

The Government may unilaterally change its COR designation.

ARTICLE G.2. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all task orders.

TBD

Primary Program Manager

ARTICLE G.3. INVOICE SUBMISSION

In addition to the requirements specified in the base contract 75N91019D00024 and FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

- a. The Contract Title is: The NCI FFRDC Bridge Contract
- b. The Task Order Title is: NIAID DMID: COVID-19 Remdesivir Study
- c. Task Order Line Items are as follows:

PRISM Line Item #	Line Item Description/Project ID	IC	CAN (with Fiscal Year)	CAN Label	Amount	End Date of Funds Availability
1	75N91020F00010; 75N91019D00024; 600 010 77 01; NIAID- DMID-DMID; CVD Preparedness and Response Supplemental Appropriations Act 2020	NIAID	0-8044363	Appropriated	\$6,680,834.00	04/02/2025
2	75N91020F00010; 75N91019D00024; 600.010.77.01; NIAID- DMID-DMID; CVD Preparedness and Response Supplemental Appropriations Act 2020	NIAID	0-8044363	Appropriated	\$10,104,139.00	04/02/2025

SECTION H - ADDITIONAL CONTRACT CLAUSES

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH & DEVELOPMENT CONTRACT

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

- a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. **Alternate I** (April 1984) of FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), is hereby deleted in its entirety and **Alternate V** (April 1984), is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCEMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning them to the Contracting Officer not later than April 3, 2020, 3:00PM EST. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding \$16,784,973 dollars.

(b) The maximum amount for which the Government shall be liable if this contract is terminated is \$16,784,973 dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Cost Plus Fixed Fee definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Cost Plus Fixed Fee proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is:

Definitization Schedule

a. Statement of Work Review 3-26-2020 - 4-01-2020

b. Issuance of Letter Contract 4-03-2020

c. Letter Contract Post Award Kick Off meeting 4-08-2020

d. Contractor Price Proposal Submittal 5-06-2020

e. POTQ/Technical Review 5-06-2020 - 5-15-2020

f. Negotiations Start 5-18-2020 - 5-22-2020

g. Request Certificate of Current Cost and/or Pricing 5-25-2020

h. Definitization of Letter Contract 5-25-2020 - 6-05-2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any

event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

4. FAR 52.216-26 - PAYMENTS OF ALLOWABLE COSTS BEFORE DEFINITIZATION (DEC 2002)

(a) Reimbursement rate. Pending the placing of the definitive contract referred to in this letter contract, the Government will promptly reimburse the Contractor for all allowable costs under this contract at the following rates:

(1) One hundred percent of approved costs representing financing payments to subcontractors under fixed-price subcontracts, provided that the Government's payments to the Contractor will not exceed 80 percent of the allowable costs of those subcontractors.

(2) One hundred percent of approved costs representing cost-reimbursement subcontracts; provided, that the Government's payments to the Contractor shall not exceed 85 percent of the allowable costs of those subcontractors.

(3) Eighty-five percent of all other approved costs.

(b) Limitation of reimbursement. To determine the amounts payable to the Contractor under this letter contract, the Contracting Officer shall determine allowable costs in accordance with the applicable cost principles in part 31 of the Federal Acquisition Regulation (FAR). The total reimbursement made under this paragraph shall not exceed 85 percent of the maximum amount of the Government's liability, as stated in this contract.

(c) Invoicing. Payments shall be made promptly to the Contractor when requested as work progresses, but (except for small business concerns) not more often than every 2 weeks, in amounts approved by the Contracting Officer. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost incurred by the Contractor in the performance of this contract.

(d) Allowable costs. For the purpose of determining allowable costs, the term "costs" includes-

(1) Those recorded costs that result, at the time of the request for reimbursement, from payment by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(2) When the Contractor is not delinquent in payment of costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for-

(i) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made-

(A) In accordance with the terms and conditions of a subcontract or invoice; and

(B) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(ii) Materials issued from the Contractor's stores inventory and placed in the production process for use on the contract;

(iii) Direct labor;

(iv) Direct travel;

(v) Other direct in-house costs; and

(vi) Properly allocable and allowable indirect costs as shown on the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(3) The amount of financing payments that the Contractor has paid by cash, check, or other forms of payment to subcontractors.

(e) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(f) Audit. At any time before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of costs audited. Any payment may be-

(1) Reduced by any amounts found by the Contracting Officer not to constitute allowable costs; or

(2) Adjusted for overpayments or underpayments made on preceding invoices or vouchers.

5. ---**Alternate I of 52.222-26** with the following fill in: "The following terms of this clause are waived for this contract: subparagraph (c)(2), (c)(3), (c)(4), (c)(5)(ii), (c)(6), (c)(8), and the phrase "on-site compliance evaluations and" in (c)(9)."

6. ---**Alternate I of 52.222-35** with the following fill in: "The following terms of this clause are

waived for this contract: in subparagraph (b), the phrase "and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans"; additionally, in subparagraph (b), the phrase "requirements of the equal opportunity clause at 41CFR 60-300.5(a)" shall be interpreted to exclude in full paragraphs 2-7, 9-10, and 12 of 41 CFR 60-300.5(a), and the phrase "take affirmative action to employ, advance in employment and otherwise" from paragraph 1 of 41 CFR 60-300.5(a)."

7. ---**Alternate I of 52.222-36** with the following fill in: "The following terms of this clause are waived for this contract: in subparagraph (a), the phrase "and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities"; additionally, in subparagraph (a), the phrase "requirements of the equal opportunity clause at 41 CFR 60-741.5(a)" shall be interpreted to exclude in full paragraphs 4-5 and 7 of 41 CFR 60-741.5(a), and the phrase "take affirmative action to employ and advance in employment individuals with disabilities, and to "from paragraph 1 of 41 CFR 60-741.5(a)."

**PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER
ATTACHMENTS SECTION J LIST OF ATTACHMENTS**

1. Statement of Work

DMID: COVID19

National Institute of Allergy and Infectious Diseases

Division of Microbiology and Infectious Diseases

Non-Severable Task Order

COVID19 Trial

March 2020

1. INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID) strives to understand, treat, and ultimately prevent the myriad of infectious, immunologic, and allergic diseases threatening the health of millions of people in the United States and around the world. Against a background of established infections, epidemics of new and old infectious diseases periodically emerge. This threat has been increasingly recognized over the last decade. Emerging/re-emerging and related respiratory viruses causing disease, such as SARS, influenza, and MERS-CoV are of particular concern given their significant morbidity and potential for rapid geographic spread. This objective supports the overall goal to better understand the diseases and therapeutic options and to improve medical outcomes for patients afflicted with the emerging and re-emerging and related respiratory viruses.

1.1 Background

The National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID), rapidly deploys resources to meet the external demands placed on NIAID to facilitate the conduct of time sensitive, high priority, global, collaborative clinical research critical to the mission of the NIAID and advancement of the National Institutes of Health (NIH) and Department of Health & Human Services (DHHS) Global Health Agendas. Fulfillment of this mission requires DMID to have the capacity to expeditiously support collaborative clinical research and conduct clinical trials both domestically and internationally.

In December 2019, the Wuhan Municipal Health Committee identified an outbreak of viral pneumonia cases of unknown cause. Coronavirus RNA was quickly identified in some of these patients. This novel coronavirus has been designated SARS-CoV-2, and the disease caused by this virus has been designated COVID-19. There were 59 confirmed cases on January 5, 2020, 278 cases on January 20, 2118 cases on January 26, rising to more than 64,000 confirmed cases and 1300 deaths as of February 14, 2020 according to various international health reporting agencies. Currently there are no approved therapeutic or prophylactic agents available for coronaviruses.

The objective of this COVID Task Order supports NIAID's goal to better understand the Coronavirus.

DMID is requesting the services of Leidos Biomedical Research, Inc. (LBR) to initiate the management, oversight, and conduct of the NIAID DMID clinical trial titled "A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19" ("Trial"). This study is an adaptive, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of novel therapeutic agents in hospitalized adult patients diagnosed with COVID-19. The study is a multicenter trial that will be conducted in up to 100 sites globally. The study

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will compare different investigational therapeutic agents to a placebo. There will be interim monitoring to introduce new arms and allow early stopping for futility, efficacy, or safety. If one therapy proves to be efficacious, this treatment will then become the control arm for comparison(s) with new experimental treatment(s). Because of the possibility that background standards of supportive care may evolve/improve over time as more is learned about successful management of COVID-19, comparisons of safety and efficacy will be based on data from concurrently randomized participants. An independent data and safety monitoring board (DSMB) will actively monitor interim data to make recommendations about early study closure or changes to study arms.

There is no benefit to NIAID until the completion and closeout of the study contemplated hereunder.

Business Assumptions are outlined under Appendix A.

2. Statement of Work

Under this Task Order, LBR shall provide the full range of services required to support DMID in conducting the Trial contemplated hereunder including, but not necessarily limited to, those listed in this Section 2.

2.1 Technical Support and Administrative Management Services

DMID requires LBR to provide the broad range of technical support and administrative management services and program- dedicated research support required to conduct the Trial domestically and internationally as requested.

LBR will establish and maintain a Coordinating Center (CC) to support the Trial with a primary base of operations co-located with NIAID at 5601 Fishers Lane, Rockville, MD.

While not intended to be an exhaustive list of the CC responsibilities, the CC will:

- A. Assist the sites in developing, implementing, and monitoring the scientific agenda
- B. Develop agenda and provide logistical support for trial related meetings.
- C. Coordinate the development, dissemination, implementation, and update of Manual of Operations and other protocol related documents.
- D. Coordinate, develop and disseminate protocols and amendments.
- E. Provide translation support of these documents as needed.
- F. Coordinate and administer research activities including, but not limited to the following:
 - Support the laboratories, and protocol teams;
 - Maintain administrative records and archives;
 - Coordinate trial related workshops, meetings and conference calls;
 - Prepare administrative and scientific reports.
- G. Develop and maintain a web-based system for dissemination of information.
- H. Provide regulatory guidance to investigators and coordinate training of staff at trial sites

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- I. Assure adherence to internationally mandated ethical and Good Clinical Practice requirements regarding conduct of research involving human subjects.
- J. Coordinate and track the publication of Network study results.
- K. Coordinate and support preparation of manuscript and scientific presentations
- L. Coordinate and administer training activities needed for the trial.
- M. Support sites during trial conduct to include maintaining a 24/7 help line / help desk to rapidly respond to inquiries about the study from participating sites.
- N. Gather evaluation data to evaluate site performance.
- O. Provide pharmacy guidance and oversight to sites and protocol teams including importation of study drugs.
- P. Coordinate and provide procurement support for sites and laboratories.
- Q. Provide Information Technology guidance to sites to enhance wide communication and data transfer activities.
- R. Track enrollment to studies .
- S. Provide guidance to sites on interfacing with the NIAID Statistical and Data Coordinating Center (SDCC) and Clinical Agent Repositories (CAR) for the study.
- T. Coordinate and support the development of laboratory capacity if needed.
- U. Support the distribution and shipment of specimens.
- V. Coordinate documents collection from sites to the Sponsor NIAID.
- W. Support the sites submission to regulatory authorities .
- X. Perform other duties as required and/or requested by NIAID to ensure optimal coordination of the multi-site, multi-county COVID19 clinical trial.

In DMID's opinion FHI360 is a vendor that is well suited to perform the CC requirements under this YT given their expansive operations domestically and globally; proven track record implementing complex clinical research protocol; and having served as the Network Coordinating Center for NIAID DCR's Special Project – SEAICRN as a subcontractor under LBR.

2.2 Conduct Broad Range of Research

DMID requires LBR to provide other services and additional scientific disciplines as required to facilitate the management and conduct of the Trial contemplated hereunder.

DMID is requesting that LBR furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to implement the Trial, while ensuring that tasks are conducted in accordance with all applicable and current country, federal, state, and local laws, codes, ordinances and regulations.

While not intended to be an exhaustive list, requirements include:

- A Administrative, Project Management and Overall Support for all Clinical Site Activities
 - 1. Manage and provide oversight of the Task Order and Subcontractor.
 - 2. Maintain frequent communications and updates with the COR on the status of the Task Order Activities

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- B. Clinical Site Identification, Site Readiness and Start-up Activities Prior to Protocol Implementation**
The Contractor shall implement, conduct, complete and provide oversight of the clinical study protocol at up to 60 sites. It is anticipated sites are identified mainly from NIAID, but also from contractor, or other collaborators.

For sites the contractor (directly or through operations center) should:

1. Distribute and collect a clinical site assessment utilizing the NIAID Site Questionnaire (Attachment A).
2. Participate in a Site Assessment and/or Site Initiation Visit(s) in conjunction with the NIAID Monitoring Contractor in person or by teleconference. Site Initiation may be done via teleconference or in person, at the sponsors discretion.
3. Assist the site in obtaining initial IRB/IEC, local regulatory authority (as applicable), and other local/institutional approvals as needed, including amendments.
4. Assist in the preparation of regulatory documentation.
5. Negotiate and execute all site budgets with Contract Officer approval.
6. Manage clinical sites in accordance with the Protocol and Manual of Procedures.
7. Support, if requested, monitoring or audits of clinical trial sites and vendors.
8. Manage investigator site payments, vendor payments, and other indirect direct costs per contract and budget.

The sites should

1. Perform all clinical study procedures as described in the Protocol, the Manual of Procedures, Quality Management Plan, Pharmacy Manual and relevant Standard Operating Procedures.
2. Perform laboratory analysis of samples as specified in the Protocol and in accordance with cGLP and cGCP regulations and in compliance with domestic and non-domestic laws and regulations.
3. Recruit and retain the study population as defined in the Protocol.
4. Identify potential problems associated with conducting this trial including but not limited to those related to recruitment, retention and implement risk mitigation strategies.
5. Maintain study records (Source Documentation Standards)
 - Documentation of source data should be in compliance with federal, state, local, institutional and international clinical research policies, and consistent with the NIAID NIAID Source Documentation Standards.
 - In carrying out the Protocol, the Contractor is required to maintain regulatory records in accordance with federal, state, local, institutional, and international clinical research policies, and consistent with the NIAID NIAID Regulatory File Document Guidelines).
6. Data Management and Quality Control
 - The Contractor shall collect study data and transfer (direct transfer, completion of CRF, etc. as appropriate) all clinical and laboratory study data to the NIAID SDCC system within seventy-two (72) hours of study visit procedures or activity as defined in the Manual of Procedures, in accordance with the Protocol.
 - Participate in data cleaning activities with the site and the SDCC.
7. Study Agents
 - Receive, inventory, store, and dispose/return (unused study agent) study product as specified by NIAID.
8. Regulatory Requirements

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- Maintain IRB/IEC approval, in addition to local regulatory authority approvals, and other local/institutional approvals as needed for amendments and other clinical research modifications.
- Provide IRB approval documentation per NIAID-CROMS
- 9. Safety Reporting
 - Report SAEs in the timeframe specified in the protocol.
 - Provide safety follow-up information to NIAID-CROMS as referenced in the Protocol.
- C. Clinical Site Training
 - 1. Assist Clinical Sites with Protocol Specific Training to include training documents posted on the NIAID SDCC Contractors website and ensure site staff have completed the appropriate training for their roles.
 - 2. Provide GCP and/or HSP Training as needed to Clinical Site Staff in accordance with NIH Requirements.
 - 3. Assist sites in navigating other study specific training for data management and study product ordering.
- D. Protocol Implementation, Conduct, Completion, Analysis and Oversight
 - 1. Protocol Specific Meeting and Teleconference Support.
 - 2. Provide for and participate in Protocol specific meeting and teleconference support.
 - 3. Prepare and distribute meeting and teleconference related materials at least 1 day in advance of all teleconferences. Prepare meeting or teleconferences minutes within 5 calendar days of the meeting or teleconference.
 - 4. Participate in close-out related meetings/teleconferences for the sites and the clinical study. Participate with the site and the SDCC in all data cleaning activities.
 - 5. In coordination with the Protocol Team, prepare a manuscript of the primary study results suitable for submission to a peer-reviewed scientific journal.
 - 6. Arrange and participate in an End of Study Results Dissemination Face-To-Face Meeting.
- E. Virology testing
 - 1. Identify, manage, and provide payment for a laboratory capable of processing the virologic endpoints of the protocol:
 - Qualitative and quantitative PCR for SARS-CoV-2 in OP swab
 - Qualitative and quantitative PCR for SARS-CoV-2 in blood

At the conclusion of the program, a consolidated final report shall be submitted to NIAID DMID summarizing accomplishments, outcomes, and impact on the overall research initiative to improve medical outcomes for patients.

COVID19

Appendix A

Business Assumptions

A. Study

1. Initial sample size is 440 subjects (includes 10% lost to follow-up). Additional enrollment will be required. This number may be increased up to 1200 based upon the true odds ratio or it may also be increased if additional therapeutic arms are added.

B. Coordinating Center

2. Ten FTE equivalents (five 100% FTE, and others with split responsibilities) - some co-located within NIAID at 5601 Fishers Lane, Rockville, MD and some located at an international location.
3. Travel – (2) persons traveling to each site two times per year

C. Sites

1. Up to 100 sites based domestically and internationally, of which the Contractor may be asked to fund up to 80 sites
2. International locations may include sites in:
 - 1) South Korea
 - 2) Singapore
 - 3) Thailand
 - 4) Japan
 - 5) Italy
 - 6) United Kingdom
 - 7) Mexico
 - 8) Other countries may be added
3. Per Site Reimbursement
 - 1) \$10k site initiation fee
 - 2) \$20k per subject enrolled
 - 3) \$10k per year for site principal investigator and staff time to maintain the study regulatory files, IRB continuing reviews, etc.



The Emmes Company, LLC

Billing Number: 000005
Invoice Number: INV-0000010836

Invoice Date: 05/14/2020

Bill To:
National Institutes of Health
Office of Financial Mngt Commercial Acct
2115 East Jefferson St., RM4B-432, MSC8500
Bethesda, MD 20892-8500

Remit To:
The Emmes Company, LLC
401 N Washington St, Ste 700
Attn: Accounting Department
(301) 251-1161
Rockville, MD 20850

Customer Number: N00005
Prime Contract Number: HHSN272201500002C
Subcontractor Number:

Cost: \$0.00
Fee: \$0.00
Total: \$0.00

Funded Value

Project Number: 13451.00.06.08AX
Project Name: 20-0006 COV ADAPTIVE TX
Project POP: 02/16/2020 to 09/05/2020
Project Manager: Ewell, Marian
Terms: NET 30
Due Date: 06/13/2020
VAT/Tax ID Number: 54-1058268

Cumulative Amount Billed: \$1,025,195.94

Billing Period From: 04/01/2020 To: 04/30/2020
Billing Currency: USD

		Current Amount	Cumulative Amount
Direct Labor		Labor Costs	Labor Costs
Total Labor Cost			
Subcontracts		Line Item Costs	Line Item Costs
O/S			
Total Non-Labor Cost			
Fringe	Fringe	Fringe Benefits	Fringe
Overhead	Indirect Cost	Indirect Cost	Indirect Cost
ITCC			
G&A			
SHC/MHC			
Total Indirect Cost			
Fee	Fee	Fee	Fee
Total Fee			
Invoice Total		\$611,555.17	\$1,025,195.94
Current Incurred Hours:	Labor Hours		
Cumulative Incurred Hours:			

I certify that all payments requested are for appropriate purposes and in accordance with the contract.

David Jenkins

From: Lee, Marina (NIH/NIAID) [C]
To: Nayak, Seema (NIH/NIAID) [E]
Cc: Gill, Ranjodh (NIH/NIAID) [E]; Sparer, Olivia (NIH/NIAID) [C]
Subject: RE: GAO audit
Date: Friday, May 1, 2020 4:37:57 PM

20-0006	\$ 7,060,538
Emmes	413,640.76
LG	310098
Sites	
BCM	439,280
Rochester	270,156
SLU	1607442
UMD	319,589
UW	1421433
VUMC	842642
Emory	1746755

Non-responsive

From: Sparer, Olivia (NIH/NIAID) [C] <olivia.sparer@nih.gov>
Sent: Friday, 1 May, 2020 3:44 PM
To: Lee, Marina (NIH/NIAID) [E] <marina.lee@nih.gov>; Nayak, Seema (NIH/NIAID) [E] <seema.nayak@nih.gov>
Cc: Gill, Ranjodh (NIH/NIAID) [E] <ranjodh.gill@nih.gov>
Subject: RE: GAO audit
Plus Emmes costs of \$644,184.70....
NEW GRAND TOTAL: \$11,483,995.70

From: Lee, Marina (NIH/NIAID) [E] <marina.lee@nih.gov>
Sent: Friday, May 1, 2020 3:35 PM
To: Sparer, Olivia (NIH/NIAID) [C] <olivia.sparer@nih.gov>; Nayak, Seema (NIH/NIAID) [E] <seema.nayak@nih.gov>
Cc: Gill, Ranjodh (NIH/NIAID) [E] <ranjodh.gill@nih.gov>
Subject: RE: GAO audit
Additions/revisions:
Totals now reflect all grant funding for these two trials as of today.

Non-responsive

20-0006: \$4,900,542 (above) + \$1,746,755 (Emory, below from RG) + \$310,098 = **\$6,957,395**
GRAND TOTAL: \$10,839,811

From: Sparer, Olivia (NIH/NIAID) [C] <olivia.sparer@nih.gov>
Sent: Friday, 1 May, 2020 3:03 PM
To: Nayak, Seema (NIH/NIAID) [E] <seema.nayak@nih.gov>
Cc: Lee, Marina (NIH/NIAID) [E] <marina.lee@nih.gov>; Gill, Ranjodh (NIH/NIAID) [E] <ranjodh.gill@nih.gov>
Subject: RE: GAO audit
Hi Seema,

Below please find the totals for the 20-0006 supplements for the six sites you asked me to look up:

BCM: \$439,280
Rochester: \$270,156
SLU (#s from Ranjodh): \$532,714 + \$1,074,728 = \$1,607,442
UMD: \$319,589
UW: \$708,920 + \$712,513 = \$1,421,433
VUMC: \$192,338 + \$650,304 = \$842,642
Total: \$4,900,542

So adding up from above/below and the \$264K for 20-0003 LG you shared via Skype:

* Marina, is anything missing? LG supplement for 20-0006?

From: Gill, Ranjodh (NIH/NIAID) [E] <ranjodh.gill@nih.gov>
Sent: Friday, May 1, 2020 10:46 AM
To: Nayak, Seema (NIH/NIAID) [E] <seema.nayak@nih.gov>
Cc: Lee, Marina (NIH/NIAID) [E] <marina.lee@nih.gov>; Sparer, Olivia (NIH/NIAID) [C] <olivia.sparer@nih.gov>
Subject: RE: GAO audit
Seema,

Non-responsive

Here are my 20-0006 Sups:

Emory 1: \$ 278,570
Emory 2 : \$ 1,468,185 (excluding 20-0003 costs) * Approximate Costs
Emory Total: \$ 1,746,755
SLU 1: \$ 532,714

Proprietary Info

V/r,
Ranjodh

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Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act